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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
LILLING, H	
ART UNIT	**PAPER NUMBER**
1808	

18M2/0529
SUGHRUE MION ZINN MACPEAK AND SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON DC 20037-3202

DATE MAILED: 05/29/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

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☒ This application has been examined ☒ Responsive to communication filed on APRIL 15, 1996 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire THREE month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☒ Copy Ex Parte Sugano decision 25USPQ 2d 1601

Part II SUMMARY OF ACTION

1. ☒ Claims 25-34 are pending in the application.

   Of the above, claims ____ are withdrawn from consideration.

2. ☐ Claims ____ have been cancelled.
3. ☐ Claims ____ are allowed.
4. ☒ Claims 25-34 are rejected.
5. ☐ Claims ____ are objected to.
6. ☐ Claims ____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed ____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ____; filed on ____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Ser No 08/458,019

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

15. Receipt is acknowledged of the request for reconsideration filed April 18, 1996.

16. Claims 25-34 are present in the instant application. Claims 1-24 were previously cancelled.

17. The rejection of Claims 25-34 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Fleno et al, U.S. 5,356,810 has been **withdrawn** in view of the persuasive arguments.

18. Claims 25-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,356,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are within the scope of the claimed subject matter.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional

rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that there is one inventor in common with the patent and the application, see MPEP 800-13, rev 1 Sept 1995, chart IIB-conflicting claims between **APPLICATION AND A PATENT**.

19. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification **stands** objected to under 35 U.S.C. § 112, first paragraph, as enabling for the claimed microorganisms in accordance with the U.S. Rules of Deposits.

It is apparent that the additional strains are required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these additional strains. See 37 C. F. R. 1.802.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest

Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

The arguments have been deemed not to be persuasive for one of ordinary skill in the art to reproduce all of the mutants encompassed by the claimed inventions.

20. Claims 25-34 **stand** rejected under 35 U.S.C. § 112, first paragraph as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make.

The following decisions which may be pertinent to the claimed language which may be extremely broad for the microorganism, see: **In re Fisher**, 168 USPQ 18, 24 (June 11 1970)

Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be

permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

In view of the broad claimed language, the above statement:

It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art..

Further decision, see **Fiers v. Sugano 25 USPQ2d.** 1601. The decision clearly states:
"Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." This above statement is complete concordance with the above decision to In re Fischer. Applicant is absolutely not entitled to the broad claimed language for the "mutant Phaffia" which "requires a precise definition, such as by structure, formula, chemical name, or physical properties,as we have held, then a description also requires that degree of specificity." Also, stated "We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definite of that substance other than by its functional utility." Applicant does not teach in the instant specification any and all mutant strains to produce pigments at a certain level but only specific mutant strains.

21. **No claim is allowed.**

22. This action has not been made Final due to the new rejection.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1808) is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1808**
May 28, 1996

HERBERT J. LILLING
PATENT EXAMINER
GROUP 180 - ART UNIT 1808

ved from its own. The trademark re not designed to serve this

'harmaceutical Co., Inc., 1992 LEXIS at *37-38 (quoting *Infor-aring House, Inc. v. Find Maga-*.Supp. 147, 163 [209 USPQ 936] 1980)).

re the *Polaroid* factors more in favor, equitable factors would nst granting it injunctive relief. circumstances of this case, the would greatly harm Gillette with-WWW much benefit. In such table relief is not warranted. *Lobo c. v. Tunnel, Inc.*, 693 F. Supp. 71, JSPQ2d 1764] (S.D.N.Y. 1988).

aw Claims

r Competition

e law cause of action for unfair n shares many common elements anham Act claims of false desig-origin and trademark infringe-*ect Fit Indus., Inc. v. Acme Quilt-nc.*, 484 F.Supp. 643, 646 [203] (S.D.N.Y. 1979), *aff'd in part, rt*, 618 F.2d 950 [205 USPQ 297] 1980), including proof of actual o recover damages, *see Perfect Fit , Inc.*, 618 F.2d at 955, and proof ihood of confusion for equitable *id.* at 953 (citing cases). As dem-above, WWW has shown neither onfusion nor a likelihood of

ion

also seeks injunctive relief under k's anti-dilution statute. N.Y. Gen. 368-d (McKinney 1984).' A claim on rests on the allegation that a is attempting to "feed[ ] upon the eputation of an established distinc-mark or name." *Allied Mainte-rp. v. Allied Mechanical Trades*, .Y.2d 538, 545, 399 N.Y.S.2d 628, N.E.2d 1162, 1165 [198 USPQ 7).

itute provides as follows:
od of injury to business reputation or on of the distinctive quality of a mark name shall be a ground for injunctive cases of infringement of a mark regis-not registered or in cases of unfair tion, notwithstanding the absence of tion between the parties or the absence asion as to the source of goods or

Courts in this circuit have previously considered such claims, noting that:

> There are three elements of such a claim: (1) distinctiveness of the mark, either that the mark is "truly of distinctive quality" or has acquired secondary meaning in the eyes of the public; (2) likelihood of dilution, either as the result of blurring of product identification or the tarnishing of an affirmative association that a mark has come to convey; and (3) predatory intent.

Lobo Enters., Inc., 693 F.Supp. at 79 (quoting *Sally Gee, Inc.*, 699 F.2d at 625-26). WWW has not put forth evidence to support any of the elements of a dilution claim. Even were the court to accept that WWW's mark is wellk-nown and has been subjected to dilution by Gillette's use of a similar mark, WWW has not shown any intent by Gillette to trade on WWW's reputation. *See Id.* at 79.

III. *CONCLUSION*

The judgment of the district court is affirmed.

Court of Appeals, Federal Circuit

Fiers v. Sugano

Nos. 92-1170, -1171

Decided January 19, 1993

PATENTS

1. Patentability/Validity — Date of invention — Conception (§115.0403)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Conception is question of law, reviewed de novo on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility.

PATENTS

2. Patentability/Validity — Date of invention — Conception (§115.0403)

Patent construction — Claims — Process (§125.1309)

Conception may occur if inventor is able to define DNA sequence by its method of preparation, but only if DNA is claimed by that method; conception of substance claimed per se, without reference to process, requires conception of its structure, name, formula, or definitive chemical or physical properties, and existence of workable method of preparation therefore cannot establish conception of subject matter of interference count in question, which is DNA sequence, having particular biological activity or function, claimed without reference to process.

3. Patentability/Validity — Specification — Written description (§115.1103)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Compliance with written description requirement of 35 USC 112 is question of fact, reviewed on appeal for clear error; interference party is entitled to benefit of earlier-filed foreign application only if specification satisfies description requirement by reasonably conveying to artisan that party had possession of claimed subject matter at time of application.

PATENTS

4. Practice and procedure in Patent and Trademark Office — Interference — Counts (§110.1703)

Patentability/Validity — Specification — Written description (§115.1103)

Specification containing statement that claimed DNA sequence is part of invention, and reference to potential method for isolating sequence, does not satisfy written description requirement of 35 USC 112, since specification does not describe DNA itself, nor even demonstrate that disclosed method would actually produce DNA in question, and since application therefore does not demonstrate that inventor had possession of claimed DNA; contention that correspondence between language of interference count and language in specification is sufficient to satisfy written description requirement is thus unpersuasive, since none of that

language particularly describes DNA sequence in interference.

5. **Practice and procedure in Patent and Trademark Office — Interference — Counts (§110.1703)**

Patentability/Validity — Date of invention — Conception (§115.0403)

Patentability/Validity — Specification — Written description (§115.1103)

Disclosure sufficient to satisfy written description requirement of 35 USC 112 for claimed DNA sequence must have same degree of specificity as disclosure which demonstrates conception, and must therefore include precise definition of DNA, such as by structure, formula, chemical name, or physical properties; interference count at issue, which purports to cover all DNA sequences that code for particular interferon, is analogous to single means claim, which has been held not to comply with Section 112, and thus language claiming all DNA sequences which achieve particular result, without defining what means will do so, is not in compliance with description requirement, even if language corresponds to that of count.

6. **Patentability/Validity — Specification — Enablement (§115.1105)**

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Enablement is question of law that is reviewed de novo on appeal; enablement requirement of 35 USC 112 is satisfied if application contains description that enables one skilled in art to make and use claimed invention.

PATENTS

7. **Practice and procedure in Patent and Trademark Office — Interference — In general (§110.1701)**

Practice and procedure in Patent and Trademark Office — Interference — Burden of proof (§110.1707)

Patentability/Validity — Specification — Enablement (§115.1105)

Prevailing party in interference that did not produce extrinsic evidence of enablement did not, thereby, fail to prove that application is enabling, since party asserting failure to comply with 35 USC 112 bears burden of persuasion on that issue, and since prevailing party therefore had no further burden to submit extrinsic evidence of enablement once examiner accepted sufficiency of specification; opposing party was not deprived of opportunity to challenge prevailing party's entitlement to Japanese application filing date, even if opposer had no opportunity to cross-examine due to prevailing party's election to stand on filing date, since opposing party had other opportunities, including during motion period, to make such challenge.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Three-way patent interference proceeding (no. 101,096), between Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (application filed Oct. 27, 1980), Walter C. Fiers (application filed April 3, 1981), and Michel Revel and Pierre Tiollais (application filed Sept. 28, 1982). From decision awarding priority of invention (DNA which codes for a human fibroblast interferon-beta polypeptide) to Sugano, et al., Fiers and Revel, et al. appeal. Affirmed.

David J. Lee, James F. Haley, Jr., and Ivor R. Elrifi, of Fish & Neave, New York, N.Y.; Roger L. Browdy, of Browdy & Neimark, Washington, D.C., for appellants.

Nels T. Lippert, of White & Case, New York, for appellees.

Before Cowen, senior circuit judge, and Michel and Lourie, circuit judges.

Lourie, J.

Walter C. Fiers, Michel Revel, and Pierre Tiollais appeal from the June 5, 1991 decision of the Patent and Trademark Office Board of Patent Appeals and Interferences, awarding priority of invention in a three-way interference proceeding, No. 101,096, to Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (Sugano). We affirm.

BACKGROUND

This interference among three foreign inventive entities relates to the DNA [1] which

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[1] DNA is deoxyribonucleic acid, a generic term encompassing the many chemical materials that genetically control the structure and metabolism of living things.

ion on that issue, and since prevailing herefore had no further burden to extrinsic evidence of enablement aminer accepted sufficiency of speci-; opposing party was not deprived of inity to challenge prevailing party's nent to Japanese application filing ven if opposer had no opportunity to camine due to prevailing party's elec- stand on filing date, since opposing ad other opportunities, including dur- tion period, to make such challenge.

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T. Lippert, of White & Case, New k, for appellees.

Cowen, senior circuit judge, and Mi- and Lourie, circuit judges.

rie, J.

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BACKGROUND

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A is deoxyribonucleic acid, a generic ncompassing the many chemical materials netically control the structure and metabo- living things.

codes for human fibroblast beta-interferon (β-IF), a protein that promotes viral resistance in human tissue. It involves a single count which reads:

> A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.

The parties filed U.S. patent applications as follows: Sugano on October 27, 1980, Fiers on April 3, 1981, and Revel and Tiollais (Revel) on September 28, 1982.[2] Sugano claimed the benefit of his March 19, 1980 Japanese filing date, Revel claimed the benefit of his November 21, 1979 Israeli filing date, and Fiers sought to establish priority under 35 U.S.C. § 102(g) based on prior conception coupled with diligence up to his British filing date on April 3, 1980.[3]

Sugano's Japanese application disclosed the complete nucleotide sequence of a DNA coding for β-IF and a method for isolating that DNA.[4] Revel's Israeli application disclosed a method for isolating a fragment of the DNA coding for β-IF as well as a method for isolating messenger RNA (mRNA) coding for β-IF, but did not disclose a complete DNA sequence coding for β-IF.[5] Fiers, who was working abroad, based his case for priority on an alleged conception either in September 1979 or in January 1980, when his ideas were brought into the United States, coupled with diligence toward a constructive reduction to practice on April 3, 1980, when he filed a British application disclosing the complete nucleotide sequence of a DNA coding for β-IF. According to Fiers, his conception of the DNA of the count occurred when two American scientists, Walter Gilbert and Phillip Sharp, to whom he revealed outside of the United States a proposed method for isolating DNA coding for β-IF, brought the protocol back to the United States.[6] Fiers submitted affidavits from Gilbert and Sharp averring that, based on Fiers' proposed protocol, one of ordinary skill in the art would have been able to isolate β-IF DNA without undue experimentation.[7] On February 26, 1980, Fiers' patent attorney brought into the United States a draft patent application disclosing Fiers' method, but not the nucleotide sequence for the DNA.

The Board awarded priority of invention to Sugano, concluding that (1) Sugano was entitled to the benefit of his March 19, 1980 Japanese filing date,[8] (2) Fiers was entitled to the benefit of his April 3, 1980 British filing date, but did not prove conception of the DNA of the count prior to that date, and (3) Revel was not entitled to the benefit of his November 21, 1979 Israeli filing date.

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[2] Revel assigned his application to Yeda Research and Dev. Co. Ltd. The real party in interest in the Fiers application has been indicated to be Biogen, Inc. The real party in interest in the Sugano application has been indicated to be Juridical Foundation, Japanese Foundation for Cancer Research.

[3] 35 U.S.C. § 102 provides in pertinent part:

> A person shall be entitled to a patent unless . . .
>
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

[4] Sugano's method involved the preparation of two populations of radioactivity-labelled cDNA probes prepared from the mRNA of fibroblast cells. One population of probes was prepared from the mRNA of induced fibroblast cells and the other population from the mRNA of non-induced cells. These probes were then exposed to a cDNA library prepared from induced cells, and the clones that only hybridized with the first probe were selected. The selected clones were then used as probes to select the full-length DNA sequence encoding β-IF, which was then sequenced.

[5] Revel's method involved preparing a cDNA library of clones from the mRNA of cells induced to produce β-IF, screening each clone for hybridization to mRNA from induced cells, eluting the hybridized mRNA, and assaying the eluted mRNAs for β-IF activity.

[6] Fiers presented his protocols and progress to date toward isolating DNA coding for β-IF at a September 21, 1979 meeting in Paris at which Sharp and Gilbert were present. Sharp and Gilbert returned to the United States on September 23 and 24, respectively. Fiers made a second presentation in Martinique on January 12, 1980. Gilbert and Sharp were both present and returned to the United States on January 15 and 17, respectively. On March 25, 1980, Fiers disclosed by telephone to his patent attorney that he had determined the entire nucleotide sequence of a DNA coding for β-IF. Fiers presented that nucleotide sequence along with a protocol for preparing the complete DNA in Switzerland on March 28, 1980. Fiers and his attorney worked from March 31 until April 2 in Ghent drafting the final portion and claims of the British application that Fiers filed on April 3, 1980.

[7] Fiers' proposed protocol involved preparing a cDNA library from the mRNA of cells induced to produce β-IF mRNA, and screening the cDNA library for a cDNA that, when introduced into a cell, would cause it to display β-IF activity.

[8] Sugano also claimed the benefit of an October 30, 1979 Japanese filing date which the Board denied. Sugano does not challenge that determination on appeal.

The Board based its conclusions on the disclosure or failure to disclose the complete nucleotide sequence of a DNA coding for β-IF.

DISCUSSION

Fiers' Case for Priority

The Board held that Fiers failed to establish conception in the United States prior to his April 3, 1980 British filing date. Specifically, the Board determined that Fiers' disclosure of a method for isolating the DNA of the count, along with expert testimony that his method would have enabled one of ordinary skill in the art to produce that DNA, did not establish conception, since "success was not assured or certain until the [β-IF] gene was in fact isolated and its sequence known." The Board relied on our opinion in *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), in which we addressed the requirements necessary to establish conception of a purified DNA sequence coding for a specific protein. Accordingly, the Board held that Fiers was entitled only to the benefit of his April 3, 1980 British application date because only that application disclosed the complete nucleotide sequence of the DNA coding for β-IF. That date was subsequent to Sugano's March 1980 Japanese priority date.

Fiers argues that the Board erroneously determined that *Amgen* controls this case. According to Fiers, the Board incorrectly interpreted *Amgen* as establishing a rule that a DNA coding for a protein cannot be conceived until one knows the nucleotide sequence of that DNA. Fiers argues that this court decided *Amgen* on its particular facts and that this case is distinguishable. Fiers' position is that we intended to limit *Amgen* to cases in which isolation of a DNA was attended by serious difficulties such as those confronting the scientists searching for the DNA coding for erythropoietin (EPO), *e.g.*, screening a genomic DNA library with fully degenerate probes. According to Fiers, his method could have been easily carried out by one of ordinary skill in the art.[9] Fiers also argues that *Amgen* held that a conception of a DNA can occur if one defines it by its method of preparation. Fiers suggests that the standard for proving conception of a DNA by its method of preparation is essentially the same as that for proving that the method is enabling. Fiers thus urges us to conclude that since his method was enabling for the DNA of the count, he conceived it in the United States when Gilbert and Sharp entered the country with the knowledge of, and detailed notes concerning, Fiers' process for obtaining it.

[1] Conception is a question of law that we review *de novo*. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81, 87 (Fed. Cir. 1986) (citing *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984)). Although *Amgen* was the first case in which we discussed conception of a DNA sequence coding for a specific protein, we were not writing on a clean slate. We stated:

> Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.

927 F.2d at 1206, 18 USPQ2d at 1021. We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.

[2] Fiers' attempt to distinguish *Amgen* therefore is incorrect. We also reject Fiers' argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the

[9] Fiers' method involved screening a cDNA library which he maintains is smaller and less complex than a genomic DNA library. Fiers also contends that his screening techniques were routine to those skilled in the art, while those skilled in the art lacked experience screening with fully degenerate probes. Fiers also notes that, in contrast to the situation with EPO in which erroneous amino acid sequence information had been published, the first thirteen amino acids of β-IF were known to the art.

it *Amgen* held that a conception of an occur if one defines it by its f preparation. Fiers suggests that ard for proving conception of a its method of preparation is essen- same as that for proving that the , enabling. Fiers thus urges us to that since his method was enabling NA of the count, he conceived it in d States when Gilbert and Sharp he country with the knowledge of, led notes concerning, Fiers' process ing it.

nception is a question of law that we *e novo. Hybritech Inc. v. Mono- ntibodies, Inc.*, 802 F.2d 1367, 231 1, 87 (Fed. Cir. 1986) (citing *Bar- mer Maschinenfabrik AG v. Mur- hinery, Ltd.*, 731 F.2d 831, 837, 221 51, 565 (Fed. Cir. 1984)). Although was the first case in which we dis- onception of a DNA sequence cod- specific protein, we were not writing n slate. We stated:

ption does not occur unless one has a l picture of the structure of the cal, or is able to define it by its d of preparation, its physical or cal properties, or whatever charac- cs sufficiently distinguish it. It is not ent to define it solely by its principal gical property, *e.g.*, encoding human ropoietin, because an alleged concep- aving no more specificity than that is y a wish to know the identity of any rial with that biological property. We that when an inventor is unable to on the detailed chemical structure of ene so as to distinguish it from other rials, as well as a method for obtain- , conception has not been achieved reduction to practice has occurred, ntil after the gene has been isolated. d at 1206, 18 USPQ2d at 1021. We etermined that, irrespective of the xity or simplicity of the method of n employed, conception of a DNA, nception of any chemical substance, s a definition of that substance other y its functional utility.

Fiers' attempt to distinguish *Amgen* re is incorrect. We also reject Fiers' ent that the existence of a workable l for preparing a DNA establishes tion of that material. Our statement gen that conception may occur, *inter* hen one is able to define a chemical by thod of preparation requires that the

ed, the first thirteen amino acids of β-IF nown to the art.

DNA be claimed by its method of preparation. We recognized that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

The present count is to a product, a DNA which codes for β-IF; it is a claim to a product having a particular biological activity or function, and in *Amgen*, we held that such a product is not conceived until one can define it other than by its biological activity or function. The difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans. While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity.

Fiers has devoted a considerable portion of his briefs to arguing that his method was enabling. The issue here, however, is conception of the DNA of the count, not enablement. Enablement concerns teaching one of ordinary skill in the art how to practice the claimed invention. *See* 35 U.S.C. § 112 (1988); *Amgen*, 927 F.2d at 1212, 18 USPQ2d at 1026. Since Fiers seeks to establish priority under section 102(g), the controlling issue here is whether he conceived a DNA coding for β-IF, not whether his method was enabling.

We conclude that the Board correctly decided that conception of the DNA of the count did not occur upon conception of a method for obtaining it. Fiers is entitled only to the benefit of his April 3, 1980 British filing date, since he did not conceive the DNA of the count under section 102(g) prior to that date.

Revel's Case for Priority

Revel bears the burden of proving entitlement to the benefit of his earlier-filed Israeli application date. *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1713 (Fed. Cir. 1988). To meet this burden, Revel must prove that his application meets the requirements of 35 U.S.C. § 112, first paragraph, *Bigham v. Godtfredsen*, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) (citing *Cross v. Iuzika*, 753 F.2d 1040, 1043, 224 USPQ 739, 741 (Fed. Cir. 1985)), which provides in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

Revel thus must show that the Israeli application contains a written description of the DNA of the count and that it is enabling.

The Board held that Revel's Israeli application did not contain a written description of a DNA coding for β-IF since it did not disclose the nucleotide sequence or "an intact complete gene." The Board, in denying Revel's request for reconsideration, rejected the argument that it is only necessary to show some correspondence between the language in the count and language in the Israeli application to satisfy the written description requirement. The Board stated:

> Moreover, what is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed. The test for sufficiency of support is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." As is apparent from our decision, we found the description in Revel's Israeli application inadequate to reasonably convey to the artisan that Revel was in possession of the invention of beta-interferon DNA [citations omitted].

Relying on *Amgen*, the Board concluded that the Israeli application was not enabling since Revel had not yet conceived the DNA of the count and "[l]ogically, one cannot . . . enable an invention that has not been conceived." Slip op. at 13.

Revel argues that the disclosure of his Israeli application satisfies the written description requirement because it contains language of similar scope and wording to that of the count. Revel cites the following passages from the Israeli application:

> The invention thus concerns also said purified m-RNAs which comprises normally up to 900-1000 nucleotides. . . . In the

same manner *it also concerns the corresponding c-DNA which can be obtained by transcription of said RNAs* [emphasis added];

It is a further object of the present invention to provide a process for the isolation of genetic material (DNA) containing the nucleotide sequence coding for interferon in human cells.

Revel points to a claim in the original Israeli application that corresponds substantially to the language of the count.[10] According to Revel, since the language of the count refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement. Revel thus urges that only similar language in the specification or original claims is necessary to satisfy the written description requirement.

[3] We disagree. Compliance with the written description requirement is a question of fact which we review for clear error. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *Utter*, 845 F.2d at 998, 6 USPQ2d at 1714. On reconsideration, the Board correctly set forth the legal standard for sufficiency of description: the specification of Revel's Israeli application must "reasonably convey[ ] to the artisan that the inventor had possession at that time of the ... claimed subject matter." Slip op. at 3 (citing *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117).

[4] An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain *mRNA* coding for β-IF.[11] A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.

[5] As we stated in *Amgen* and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.

Because the count at issue purports to cover all DNAs that code for β-IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112. *See In re Hyatt*, 708 F.2d 712, 218 USPQ 195, 197 (Fed. Cir. 1983) ("the enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration.") Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.

The Board's determination that the Israeli application does not contain a written description of a DNA coding for β-IF was thus not clearly erroneous. The Board correctly determined that Revel is not entitled to the benefit of his November 1979 Israeli application since it fails to satisfy the written description requirement of section 112.[12]

Sugano's Case for Priority

The Board held that Sugano established entitlement to his March 19, 1980 Japanese filing date because the disclosure of his Japanese application contains the complete and correct sequence of the DNA which codes for β-IF, along with a detailed disclosure of the method used by Sugano to obtain that DNA. The Board rejected Fiers' argument that Sugano's March 1980 application is not enabling, since Fiers presented only attorney argument that was "unsupported by compe-

[10] Claim 22 of Revel's original Israeli application reads:

The DNA coding for a polypeptide having interferon activity insertable in a vector, such as plasmid PBR-322, and having up to 900-1000 nucleotides.

[11] According to Fiers, Revel's Israeli application also fails the written description requirement because the mRNA disclosed in the application encodes a protein weighing 23,000 daltons which is interleukin-6, not β-IF. The Board did not premise its decision on this point, and, since we determine that Revel's application does not describe the DNA of the count, we need not reach it either.

[12] In light of our disposition of the written description requirement question, we do not address whether Revel's Israeli application satisfies the enablement requirement.

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tent evidence, entitled to little or no weight and [was] unpersuasive in any event." Slip op. at 12.

Fiers argues that Sugano failed to prove that his application is enabling because he did not produce extrinsic evidence showing enablement. Fiers also argues that the Board erroneously imposed a burden on him to show that Sugano's application is not enabling when, in fact, Fiers had no right to submit rebuttal evidence once Sugano elected to rely solely on his Japanese application.

[6,7] Enablement is a question of law that we review *de novo*. *Amgen*, 927 F.2d at 1212, 18 USPQ2d at 1026. Enablement requires that the application " 'contain a description that enables one skilled in the art to make and use the claimed invention.' " *Id.*, (citing *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)). "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). "[A]ny party making the assertion that a U.S. patent specification or claims fails, for one reason or another, to comply with § 112 bears the burden of persuasion in showing said lack of compliance." *Weil v. Fritz*, 601 F.2d 551, 555, 202 USPQ 447, 450 (CCPA 1979). Thus, once the examiner accepted the sufficiency of Sugano's specification, Sugano had no further burden to prove by extrinsic evidence that his application was enabling; the Board correctly determined that it was Fiers (or Revel) who then had to prove that Sugano's application was not enabling. Even if Fiers had no opportunity to cross-examine Sugano because Sugano elected to stand on his filing date, Fiers had other opportunities, including during the motion period, to challenge Sugano's entitlement to his Japanese application filing date. Thus, he did not lack opportunity to challenge.

We conclude that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for β-IF and the Board did not err in determining that Fiers presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for β-IF and thus "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for β-IF]." *See Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117. The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of section 112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

CONCLUSION

The Board correctly awarded priority of invention to Sugano. Accordingly, the decision of the Board is

AFFIRMED.

District Court, D. Massachusetts

Enbee Plastics Inc. v. Heritage Albums Inc.

No. 91-30161-F

Decided October 26, 1992

PATENTS

1. Infringement — Tests (§120.09)

Patent owner's scientific study which compares strength and adhesive bond of declaratory judgment plaintiff's photograph pages with strength and adhesive bond of "Post-It" notes is of no relevance to whether plaintiff's adhesive exhibits pressure-sensitive qualities of kind and degree disclosed by patent in suit.

2. Infringement — Literal infringement (§120.05)

Summary judgment of non-infringement is warranted in declaratory judgment action brought by manufacturer of photograph album pages, in view of patent owner's failure to demonstrate triable issue of fact on issue of whether accused pages use pressure-sensitive adhesive as called for by patent in suit.

Particular patents — General and mechanical — Photo albums

4,702,026, Shaine, method of making pages for photo albums and pages thereby formed, declaratory judgment plaintiff's mo-